

Press Release

## Eurocor GmbH announces presentation of Valentines Trial II results at CRT2012

- **DIOR® drug-eluting balloon shows effective and safe treatment for de novo lesions**
- **Treatment with DIOR® Paclitaxel-eluting balloon shows an overall TLR rate of 2.9% at 8 months post treatment**

**Washington DC, USA | Bonn, Germany | Bengaluru, India - February 13, 2012**

Eurocor GmbH, an Opto Circuits group company, presented the eight month follow-up data from the Valentines Trial II Global Registry on February 7 during the iMPACT Trial Session at CRT2012 in Washington D.C., USA. The multi-center, international, short-term Valentines-registry was conducted with an objective to assess the efficacy of the Paclitaxel-eluting balloon DIOR® DEB for *de novo* lesions at 6-9 months follow-up. 103 patients suffering from *de novo* lesions were enrolled by 38 Investigators from 16 countries starting February 14<sup>th</sup> up to March 31<sup>st</sup> 2011. The initial eight-month follow-up data have been unveiled by Dr. Antonio Serra (Barcelona, Spain), one of the Principle Investigators (PI) during the conference. A follow-up rate of 99% was reached with a 50.5% on-site Clinical Monitoring. The trial was carried out by three Principal Investigators: Prof. Dr. Fazila Malik (Dhaka, Bangladesh), Dr. Alfredo Rodriguez (Buenos Aires, Argentina) and Dr. Antonio Serra (Barcelona, Spain).

**The Results:** The eight-month results convincingly show that the DIOR® DEB is a safe and effective treatment for cases of *de novo* lesions. The treatment with DIOR® DEB resulted in a very low overall target lesion revascularization (TLR) rate of 2.9% and a target vessel revascularization (TVR) rate of 6.9%. Also the overall major adverse cardiac event (MACE) rate of 8.7% was remarkable low. The preliminary late lumen loss (LLL) upon angiographic follow-up of a small subset of patients was  $0.30 \pm 0.36$  mm and  $0.33 \pm 0.37$  mm for the in-DEB segment and traditional in-segment analyses, respectively. A subgroup analysis of the patients suffering from diabetes (28.2%) show that the DIOR® DEB is effective in this population with a single digit TLR rate of 6.9% and a TVR rate of 13.8% at 6-9 months follow-up post treatment. The non-diabetic group of patients shows a TLR rate of 1.4% and a TVR rate of 4.1% at 6-9 months follow-up.

Dr. Antonio Serra commented: "The results of the Valentines Trial II data confirm the excellent results we obtained already in the Spanish Multicenter Registry which investigated safety and efficacy of DIOR® DEB treatment for *de novo* lesions in small vessels. With the now available results for Valentines Trial II we could prove that this is also true for *de novo* lesions in vessel with diameter of  $\geq 2.5$ mm."

Dr. Rembert Pogge von Strandmann, Director Clinical Department said: "We are happy to see furthermore positive results and clinical evidence of our DIOR® drug-eluting balloon in several clinical studies. We are confident that our DEB technology will result in significant therapeutic advantages for the patients and show a promising alternative therapeutic treatment option in the field of vascular interventions. The DIOR® DEB can be considered as a good treatment option for patients suffering from stenotic lesions, in-stent restenose or *de novo* lesions."

**Detailed Trial Results available at: [www.valentines-trial.com](http://www.valentines-trial.com) and [www.crtonline.org](http://www.crtonline.org)**

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### About Eurocor GmbH:

Eurocor is a rapidly growing European Life Sciences Technology Corporation specializing in the research, development and manufacture of cardiovascular and endovascular products. Eurocor provides interventional physicians with innovative coronary stent technologies and special cardiovascular and endovascular devices, manufactured in Bonn. Products are indicated for minimally invasive cardiovascular and peripheral surgery and comply with biological and biomechanical principles to offer highly flexible, adaptable solutions. Extensive research and development, close clinician collaboration, outstanding quality standard philosophy and global scientific alliances lead to optimization of clinically effective technologies. Eurocor has designed an innovative method for balloon catheter drug delivery with high patient compliance. One heartbeat ahead™ – with innovative products such as DIOR® and FREEWAY™.

Eurocor GmbH is a subsidiary of Opto Eurocor Healthcare Ltd. and is part of the Opto Circuits Group.

For more information, please visit [www.eurocor.com](http://www.eurocor.com)

### About: [Opto Circuits \(India\) Ltd.](#)

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Opto Circuits (India) Ltd. (OCI) is a multinational medtech company in the business of design, development, manufacture and marketing of healthcare equipment and medical interventional products. The product profile includes USFDA-listed, CE-marked cardiac and vital signs monitoring systems, anesthesia and respiratory care equipment, automated external defibrillators, stents, PTA balloons, catheters, body implants and consumables. Some of OCI's well-known brands are [Cardiac Science](#), [Criticare](#), [Eurocor](#), [Ormed](#), [Mediaid](#) and [Unetixs](#). The company's key markets are North America, Europe and BRIC countries.

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